



Sec 4 3/26/98

MAR 13 1998

Mr. Harry F. Hester
President
Dee Cee Laboratories, Inc.
304 Dee Cee Court
P.O. Box 383
White House, Tennessee 37188-0383

Dear Mr. Hester:

This is in response to your letters of October 20 and October 21, 1997 to the Food and Drug Administration (FDA) pursuant to 21 U.S.C. 343(r)(6) (section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act (the Act)). Your submission states that Dee Cee Laboratories, Inc. is making the following claims, among other claims, for the products:

Echinacea with Goldenseal Root

"Echinacea with goldenseal root is one of the most popular dietary supplement combinations for promoting well being and natural resistance during cold and flu season"

Echinacea Angustifolia Root

"Echinacea is now used by people worldwide who enjoy its ability to promomte [sic] general well being and support resistance during cold and flu season"

Echinacea Purpurea Root

"Echinacea is now used by people worldwide who enjoy its ability to promomte [sic] general well being and support resistance during cold and flu season"

Echinacea Plus

"Echinacea is now used by people worldwide who enjoy its ability to promomte [sic] general well being and support resistance during cold and flu season"

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21 U.S.C. 343(r)(6) makes clear that a statement included in labeling under the authority of that section may not claim to diagnose, mitigate, treat, cure, or prevent a specific disease or class of diseases. The statements that you are making for these products suggest that they are intended to prevent, treat or mitigate a disease, namely the common cold and influenza. These claims do not meet the requirements of 21 U.S.C. 343(r)(6). These claims suggest that these products are intended for use as drugs within the meaning of 21 U.S.C. 321(g)(1)(B), and that they are subject to regulation under the drug provisions of the Act. If you intend to make claims of this nature, you should contact FDA's Center for Drug Evaluation and Research (CDER), Office of Compliance, HFD-310, 7520 Standish Place, Rockville, Maryland 20855.

Please contact us if we may be of further assistance.

Sincerely,

James T. Tanner, Ph.D.
Acting Director
Division of Programs and Enforcement Policy
Office of Special Nutritionals
Center for Food Safety
and Applied Nutrition

Copies:

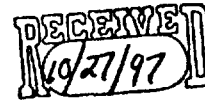
FDA, Center for Drug Evaluation and Research, Office of Compliance, HFD-300
FDA, Office of the Associate Commissioner for Regulatory Affairs, Office of
Enforcement, HFC-200
FDA, Nashville District Office, Office of Compliance, HFR-SE340

cc:

HFA-224 (w/incoming)
HFA-305 (docket 97S-0163)
HFS-22 (CCO, JGordon)
HFS-456 (File)
HFS-450 (file, r/f)
HFD-310 (BWilliams)
HFD-314 (Aronson)
HFS-600 (Reynolds)
HFS-605 (Bowers)
GCF-1 (Nickerson, Dorsey)
r/d:HFS-456:RMoore:3/12/98
Init:GCF-1:LNickerson:3/12/98
f/t:HFS-456:rjm:3/12/98:docname:55410.adv:disc26

DEE CEE LABORATORIES, INC.

304 Dee Cee Court / P.O. Box 383
White House, Tennessee 37188-0383
Phone 615-672-4987



October 21, 1997

Office of Special Nutritionals
Center for Food Safety and Applied Nutrition
Food and Drug Administration
200 "C" Street, S.W. (HFS-455)
Washington, D.C. 20204

To Whom It May Concern:

Dee Cee Laboratories, Inc. is marketing "Echinacea Plus" under the following labels - Dee Cee Laboratories, Wonder Laboratories and Foster Regal Laboratories - with the following statement of nutritional support:

Echinacea is now used by people worldwide who enjoy its ability to promote general well being and support resistance during cold and flu season.* We utilize the same species and standardized extracts of Echinacea which have been scientifically researched for their beneficial effects on human health. Our special formulation contains three types of Echinacea to help ensure you receive all the beneficial constituents found in this exceptional herb--standardized Echinacea root extract and two species of wildcrafted Echinacea root powder. This balanced and scientific approach to formulation of dietary supplements helps ensure optimum results.

*This statement has not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure or prevent any disease.

Respectfully submitted,

DEE CEE LABORATORIES, INC.

A handwritten signature in cursive script that reads "Harry F. Hester".

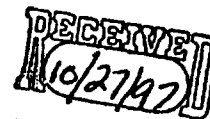
Harry F. Hester
President

HFH/ss

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DEE CEE LABORATORIES, INC.

304 Dee Cee Court / P.O. Box 383
White House, Tennessee 37188-0383
Phone 615-672-4987



October 21, 1997

Office of Special Nutritionals
Center for Food Safety and Applied Nutrition
Food and Drug Administration
200 "C" Street, S.W. (HFS-455)
Washington, D.C. 20204

To Whom It May Concern:

Dee Cee Laboratories, Inc. is marketing "Echinacea Purpurea Root" under the following labels - Dee Cee Laboratories, Wonder Laboratories and Foster Regal Laboratories - with the following statement of nutritional support:

Echinacea is now used by people worldwide who enjoy its ability to promote general well being and support resistance during cold and flu season.* We utilize the same species of echinacea which has been scientifically researched for its beneficial effects on human health.

*This statement has not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure or prevent any disease.

Respectfully submitted,

DEE CEE LABORATORIES, INC.

Harry F. Hester
Harry F. Hester
President

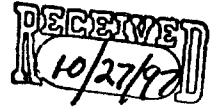
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DEE CEE LABORATORIES, INC.

304 Dee Cee Court / P.O. Box 383
White House, Tennessee 37188-0383
Phone 615-672-4987

October 21, 1997



Office of Special Nutritionals
Center for Food Safety and Applied Nutrition
Food and Drug Administration
200 "C" Street, S.W. (HFS-455)
Washington, D.C. 20204

To Whom It May Concern:

Dee Cee Laboratories, Inc. is marketing "Echinacea Angustifolia Root" under the following labels - Dee Cee Laboratories, Wonder Laboratories and Foster Regal Laboratories - with the following statement of nutritional support:

Echinacea is now used by people worldwide who enjoy its ability to promote general well being and support resistance during cold and flu season.* We utilize the same species of echinacea which has been scientifically researched for its beneficial effects on human health.

*This statement has not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure or prevent any disease.

Respectfully submitted,

DEE CEE LABORATORIES, INC.

A handwritten signature in cursive script that reads "Harry F. Hester".

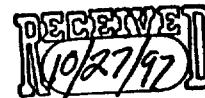
Harry F. Hester
President

HFH/ss

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DEE CEE LABORATORIES, INC.

304 Dee Cee Court / P.O. Box 383
White House, Tennessee 37188-0383
Phone 615-672-4987



October 20, 1997

Office of Special Nutritionals
Center for Food Safety and Applied Nutrition
Food and Drug Administration
200 "C" Street, S.W. (HFS-455)
Washington, D.C. 20204

To Whom It May Concern:

Dee Cee Laboratories, Inc. is marketing "Echinacea with Goldenseal Root" under the following labels - Dee Cee Laboratories, Wonder Laboratories and Foster Regal Laboratories - with the following statement of nutritional support:

Echinacea with Goldenseal Root is one of the most popular dietary supplement combinations for promoting well being and natural resistance during cold and flu season.* This special formulation contains the two Echinacea species most often scientifically researched for their ability to support human health. Each capsule also contains a synergistic combination of herbs traditionally utilized by health care practitioners. This balanced and scientific approach to formulation of dietary supplements helps ensure optimum results.

*This statement has not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure or prevent any disease.

Respectfully submitted,

DEE CEE LABORATORIES, INC.

Harry F. Hester
Harry F. Hester
President

HFH/ss

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